



# NBAC Facts

## **Ethical and Policy Issues in the Oversight of Human Research in the United States**

At the request of the President, NBAC has begun an examination of the current federal system for the protection of human subjects in research.<sup>i</sup> The report will include a review of the relevant statutes and regulations, with particular attention to the effectiveness of the Common Rule and the additional protections for vulnerable populations, and the applicability of those protections to the full range of government-sponsored research activities involving humans. It also will examine the strengths and the weaknesses of the current regulatory framework under which human subjects are protected. The report will make recommendations to ensure that all research involving humans is conducted ethically.

### **Background**

Since its inception, NBAC has examined ethical issues related to human research. To date, NBAC has submitted four separate reports<sup>ii</sup> to the President, each of which contains recommendations regarding particular aspects of human subjects protection.

On May 4, 1999, NBAC wrote to the President indicating areas of concern and preliminary findings regarding oversight of human research, some of which required further action by the Federal Government. The key concerns identified in NBAC's letter were:

- Federal protections for persons serving as subjects in research do not yet extend to all Americans.
- Despite widespread implementation of federal regulations by those departments and agencies sponsoring substantial amounts of biomedical research, a number of departments and agencies who sponsor primarily non-biomedical research or little research overall have failed to implement fully these federal protections.
- Federal protections do not always include specific provisions for especially vulnerable populations of research subjects.
- Many federal agencies find the interpretation and implementation of the Common Rule confusing and/or unnecessarily burdensome.
- Federal protections are difficult to enforce and improve effectively throughout the Federal Government, in part because no single authority or office oversees research protections across all government agencies and departments.
- New techniques are needed to ensure implementation at the local level.

### **National Bioethics Advisory Commission**

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## Issues NBAC Will Address

The report will address two major areas: (1) the adequacy of the current regulatory framework and structure and (2) the institutional review board system (IRBs). Among the issues the report will specifically address are:

- How research involving humans is defined, and whether other related activities warrant IRB review
- Alternatives to the current federal regulatory structure of oversight and rulemaking for human research
- Options for monitoring and ensuring compliance with federal regulatory protections
- The scope of federal regulatory protections and whether they should be extended to the private sector
- Identification and protection of vulnerable populations
- Options for oversight of research involving unique or high risks to humans
- Mechanisms to improve the functions of IRBs
- Education and training of IRB members, institution officials, and investigators
- Quality control mechanisms, including audit, certification, site visits, and accreditation
- Resource needs and infrastructure

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*The National Bioethics Advisory Commission (NBAC) was established by Executive Order 12975 in October 1995 to advise the National Science and Technology Council and other appropriate government entities regarding bioethical issues arising from research on human biology and behavior. NBAC's first priority as directed in its Executive Order, was to "consider the protection of the rights and welfare of human research subjects; and issues in the management and use of genetic information." The Executive Order encouraged NBAC to identify other bioethical issues for the purpose of providing advice and recommendations. Chaired by Princeton University President Harold T. Shapiro, Ph.D., the Commission is comprised of physicians, theologians, ethicists, scientists, lawyers, psychologists, and mental health advocates.*

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<sup>i</sup> Remarks by the Honorable Neal F. Lane, Assistant to the President for Science and Technology, at the 35<sup>th</sup> meeting of the National Bioethics Advisory Commission, October 22, 1999. The full text is available at [www.bioethics.gov](http://www.bioethics.gov).

<sup>ii</sup> *Cloning Human Beings* (June 1997); *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity* (December 1998); *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (August 1999); *Ethical Issues in Human Stem Cell Research* (September 1999)